K111635 1 of 2

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Submitted by:	Smith & Nephew, Inc. Orthopaedic Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	June 9, 2011
Contact Person and Address:	Megan Bevill, Regulatory Affairs Project Manager T (901) 399-5340 F (901) 566-7086
Name of Device:	Smith & Nephew, Inc. R3 Constrained Liner
Common Name:	Acetabular Liner, Constrained
Device Classification Name and Reference:	21 CFR 888.3310 Hip joint metal/polymer constrained cemented or uncemented prosthesis
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	KWZ

SEP - 9 2011

Device Description

The R3 Constrained Liners were previously cleared for market via premarket notification K083566. In August of 2010, Smith & Nephew launched a voluntary recall of the devices due to reports of intraoperative dislocations. The subject devices have been modified to address the intraoperative failure mode. Design features have been incorporated into the inner locking and support ring components of the R3 Constrained Liner construct which increase the device's resistance to dislocation under dynamic loading.

The R3 Constrained Liners are available with inner diameters of 22 and 28mm and outer diameters from 52mm through 66/70mm. The devices are assembled from components that are made of ASTM F75 CoCr, ASTM F90 CoCr, ASTM F1472 Ti-6Al-4V, and ASTM F648 UHMWPE.

Technological Characteristics

Mechanical testing has been conducted to address the attachment loads (push-in, push-out, shuck-out) of the R3 Constrained Liner components as well as to address the new failure mode (dislocation). A review of the results indicates that the R3 Constrained Liners are equivalent to existing, legally marketed predicate devices with regards to mechanical performance and that there are no new issues related to the safety and effectiveness of the subject devices. Clinical data was not needed to support the safety and effectiveness of the subject devices.

Intended Use

The R3 Constrained Liner Acetabular System is a cemented or uncemented prosthesis intended to replace a hip joint. The Constrained Liner is intended for primary or revision patients at high risk for hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability and for whom all other options to constrained acetabular components have been considered. The R3 Constrained Liner is intended for single use only.

Substantial Equivalence Information

The subject devices are identical in function, intended use, indications for use, and material composition, and very similar in overall design to the R3 Constrained Liners cleared via premarket notification K083566.

Table 1: Substantially equivalent predicates to the R3 Constrained Liner

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	R3 Constrained Liner	K083566	3/3/2009
Smith & Nephew, Inc.	Reflection Constrained Liners	K021803 K033442	12/19/2002 11/26/2003

Conclusion

As previously noted, this Traditional 510(k) Premarket Notification is being submitted to request clearance for the modified R3 Constrained Liners. Based on the similarities to the predicate components and a review of the mechanical testing performed, the devices are substantially equivalent to above predicate constrained hip systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Smith & Nephew, Inc.
% Ms. Megan Bevill
Regulatory Affairs Project Manager
1450 Brooks Road
Memphis, Tennessee 38116

SEP - 9 2011

Re: K111635
Trade/Device Name: R3 Constrained Liner
Regulation Number: 21 CFR 888.3310
Regulation Name: Hip joint metal/polymer constrained cemented or uncemented prosthesis
Regulatory Class: II
Product Code: KWZ
Dated: June 9, 2011
Received: June 13, 2011

Dear Ms. Bevill:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification
Indications for Use Statement

510(k) Number (if known): K111635

Device Name: R3 Constrained Liner

Indications for Use:

The R3 Constrained Liner Acetabular System is a cemented or uncemented prosthesis intended to replace a hip joint. The Constrained Liner is intended for primary or revision patients at high risk for hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability and for whom all other options to constrained acetabular components have been considered. The R3 Constrained Liner is intended for single use only.

Prescription Use __X__ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801.109) (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Mekkerm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111635